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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,113	06/27/2003	Scott B. Bintrim	DAS-101XC2	6438

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
BUGAISKY, GABRIELE E	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,113	BINTRIM ET AL.	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-11 and 20-23, drawn to methods of screening *Paenibacillus* isolates for genes encoding crystal proteins, classified in at least class 435, subclass 6

II. Claim 2 , drawn to a method of screening for a toxin by feeding culture supernatants to lepidopterans, classified in class 424, subclass 9.2 .

III. Claims 12-15, and 19 drawn to isolated *Paenibacillus* crystal proteins and a method of controlling lepidopterans , classified in class 514, subclass 12.

IV. Claims 16-18, drawn to isolated nucleic acids encoding *Paenibacillus* crystal proteins, and constructs containing them classified in class 435, subclass 410.

V. Claim 24, drawn to purified *Paenibacillus* strains, classified in class 435, subclass 252.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Group II merely requires assay of a culture supernatant , whereas Group I requires purification of a compound..

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. A protein is not defined by its method of isolation.

Inventions IV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used to transform cells in order to produce proteins by recombinant means.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The assay method using a purified compound does not require the use of two specific pure cultures..

Inventions II and each of III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. With respect to groups III and IV, the screening method does not utilize the isolated compounds of those groups. With respect to Group V, . a specific bacterial strain is not defined by it method of identification. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions

have different modes f operation. Although a protein is related to a nucleic acid in that the nucleic acids encode the protein, the protein can be obtained by chemical synthesis.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Although bacterial cultures contain specific proteins, they arte not present in purified form; further, the protein can be made by recombinant means in other transformed cells or by chemical synthesis.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Although the nucleic acid is present in the bacteria the bacteria do not require the nucleic acid to be isolated; further , the nucleic acid can be used in other unrelated bacterial strains to make a protein by recombinant means..

.Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject mater, different classifications and different searches, restriction for examination purposes as indicated is proper.

Should Group I be elected, it is noted that the claimed method is an improper Markush group, in that the assay procedures screen different chemical compound: Thus, further

restriction is required to one of the following subgroups and claims will be examined only for elected subject material:

IA: A method of screening utilizing nucleic acid probes or primers, claims 1, 3-9, 11 and 20-23. Applicant is required to select a single gene for the probe or primer pair from one gene.

IB: A method of screening utilizing antibodies, claims 1, 3-6, and 10 .

Should Group IIII be elected, further restriction is necessary:

This application contains claims directed to the following patentably distinct compounds, (which have different primary structures) of the claimed invention: specific polypeptides of SEQ ID NO: 3, 5, ,7 ,9, 11, 13,1 5, ,18, 19, 33, 36, 37, 39 and 41. Applicant is required under 35 U.S.C. 121 to elect a single disclosed compound for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner will examine an identified protoxin along with the mature form. Currently, all claims of Groups III are generic.

Also, should Group II be elected, further restriction is required:

This application contains claims directed to the following patentably distinct compounds, (which have different primary structures) of the claimed invention: specific nucleotide sequences encoding SEQ ID NO: 3, 5 , 7 ,9, 11, 13, 33, 36, 37, 39 and 41. Applicant is required under 35 U.S.C. 121 to elect a single disclosed compound for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims of Group IV are generic.

Applicant is advised that a reply to this requirement must include an identification of the peptide or nucleic acid that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election

This election requirement is not be construed as a species election, as these compounds do not share a common primary structure and appear to be patentably distinct.

Should applicant traverse on the ground that these different compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1656